

## Module 3: Ethical CEI



In this module, we discuss guiding principles for ethical CEI, how to apply them, and their challenges. Elements of ethical engagement and involvement that are discussed include transparency, consent to participate, inclusion and implementing cycles of continuous learning (adaptive research cycles). We look at power dynamics and their implications in the context of delivering CEI. We discuss key principles of safety in CEI and why ethical considerations are an important part of data sharing. Finally, we explore how CEI can respond to health needs which have not been met.

### INTRODUCTION

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#### ☰ Introduction

### GUIDING PRINCIPLES FOR ETHICAL ENGAGEMENT

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#### ☰ Guiding principles for ethical engagement

#### ☰ Incorporating ethics into CEI

#### ☰ Transparency

#### ☰ Consent to participate in CEI

 **Inclusion**

 **Adaptive research cycles**

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**POWER DYNAMICS IN CEI**

 **Power dynamics in CEI**

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**SAFETY**

 **Safety**

 **Minimising harm (safety)**

 **Data sharing**

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**CEI AND HEALTHCARE PROVISION**

 **CEI and healthcare provision**

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**SUMMARY**

 **Summary**

# Introduction

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Engaging and involving community members in global health research requires a supportive approach that is guided by ethical principles and ensures inclusion, respect and dignity.

There is some overlap between the ethical principles of research and the ethical principles of community engagement and involvement (CEI). However, because engagement involves partnership building, it brings its own unique set of ethical considerations.

In this module, we discuss guiding principles for ethical CEI, how to apply them and their challenges. Elements of ethical engagement and involvement that are discussed include transparency, consent to participate, inclusion and implementing cycles of continuous learning (adaptive research cycles). We look at power dynamics and their implications in the context of delivering CEI. We discuss key principles of safety in CEI and why ethical considerations are an important part of data sharing. Finally, we explore how CEI can respond to health needs which have not been met.

## **Aims**

- To help learners understand the essential role of ethics in community engagement and involvement (CEI) in global health research.
- To build learners' capacity to incorporate ethical principles and practices into CEI in health research.

## **Learning Outcomes**

By the end of the module, you will be able to identify and describe:

- how to apply ethical principles in a CEI process
- why transparency and inclusion are crucial principles of CEI
- how ethical principles can guide consent activities and adaptive research cycles
- the types of power dynamics in CEI, and their implications
- key principles of safety in CEI including anonymity, confidentiality and safeguarding
- why ethical considerations such as risks, benefits and ownership are important elements of data sharing
- how CEI can identify health needs that lie beyond a research topic

## **A note on terms**

In this course, CEI is understood to mean:

An active involvement of the community throughout the research process, using participatory approaches and working in partnership with all key stakeholders.

CEI includes a range of activities which involve interactions between researchers, community members and stakeholders, aimed at improving the relevance, value and conduct of health research.

Below is a glossary of common terms you can use to help guide your CEI journey. We have also hyperlinked some of the key terms as they appear throughout the module to this glossary.

*Select the grey box to download the glossary.*



**Glossary.pdf**

1 MB



**CONTINUE**

## Guiding principles for ethical engagement

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In this section, we look at ethical principles of CEI including transparency and inclusion. We discuss how ethical principles can be incorporated in practice and consider some of the challenges. We explore the process of consent in CEI and discuss the role of adaptive research cycles.

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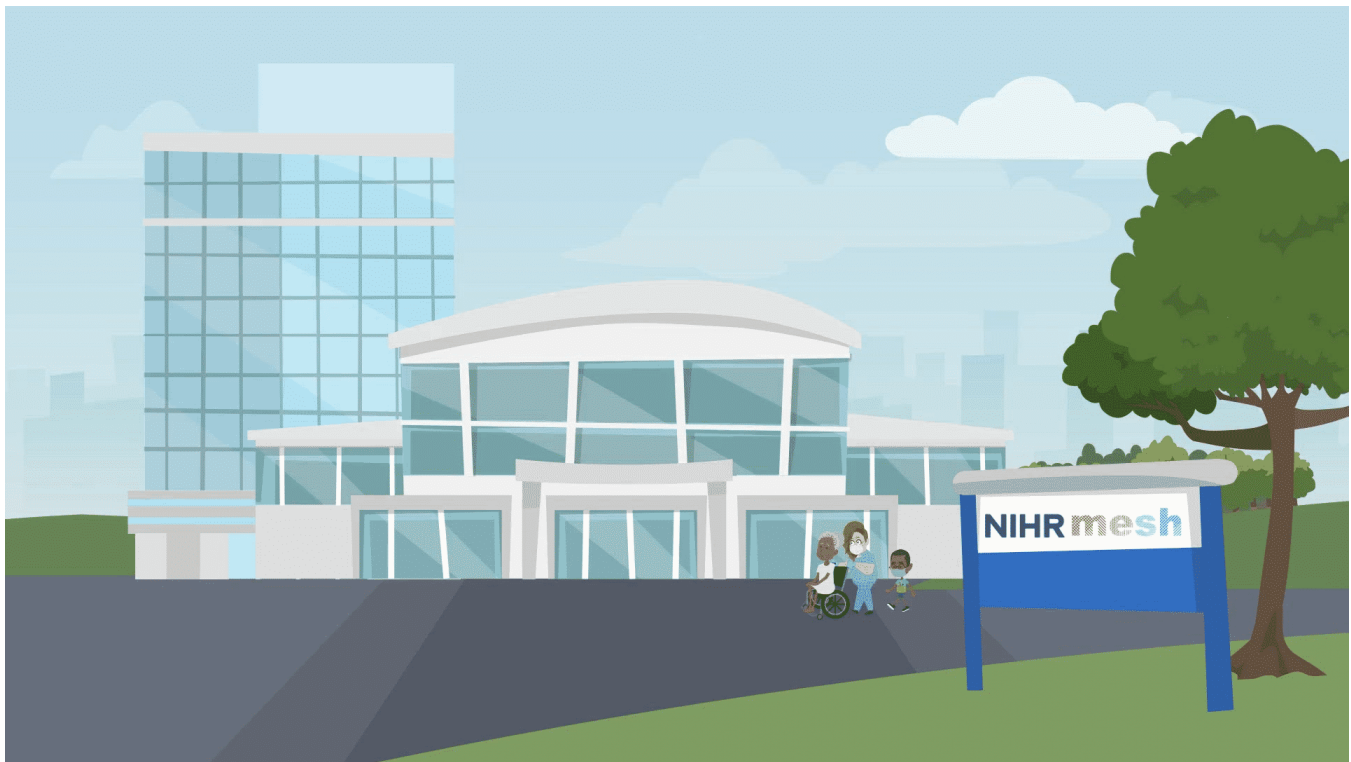
# Incorporating ethics into CEI

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Take a few moments to consider the following question and write down your answer: What do the words '**ethics**' and '**bioethics**' mean to you?

Watch the video which discusses the meaning of ethics and bioethics, and how ethics can be incorporated into CEI.

*Select the play symbol below. Closed captions are available by selecting 'CC'. The transcript can be viewed underneath by selecting the '+' symbol.*



## Video Transcript

Ethics and bioethics can be defined as follows:

Ethics: moral principles that govern a person's behaviour or the way an activity is carried out.

Bioethics: the ethics of medical and biological research.

It is crucial to build ethics into CEI to ensure that your approach to engagement and involvement is moral, responsible, fair and honest, and that it protects the rights, choices, dignity and confidentiality of participating community members.

It is not yet a standard requirement for ethics review committees to assess and approve CEI activities that are included as part of a research project. This does not mean that CEI is free from ethical challenges and potential harms. If planned engagement and involvement activities have not undergone ethical review and endorsement, institutional supervision can help to ensure the ethical conduct of CEI.

For example, undertaking CEI with people living with HIV, if not very carefully planned and implemented, could accidentally reveal individuals' HIV status to the wider public, which would be unethical.

CEI can be started in an ethical way by ensuring that community members who are invited to a CEI activity or event have been fully informed about the CEI purpose and process right from the beginning.

The way in which potential participants are informed about CEI will depend on the number of people who will be involved, the duration of the CEI process, and the context (the place and

circumstances) in which the CEI will be carried out.

When CEI involves working over a period of time with a small number of community members (for example, a focus group), information about the CEI process can be provided by bringing the group together in an introductory meeting.

A CEI introductory meeting provides an opportunity for discussion where questions can be raised and concerns addressed, among all those involved before activities begin.

A CEI introductory meeting can be held as an in-person (face-to-face) meeting or online, depending on community members' access to the internet.

When CEI involves large numbers of community members, information about the engagement activity (for example, a theatre performance or film showing with a community audience) can be shared using flyers, posters, radio announcements, community meetings or via online community platforms.

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What might community members want to know?

Take a few moments to consider what you think community members might want to know before they decide to take part in CEI.



Information that can help community members to make a well-informed decision about whether they wish to participate in CEI includes:

- The aims, objectives, purpose and value of the research project and the CEI.



- Details of other [stakeholders](#) who may be involved, for example, institutions, organisations and groups.

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### CEI activities and intended benefits

Match the CEI activity with its intended benefit. *Select one benefit per statement. Select 'submit' after each activity statement.*

Co-develop some rules of engagement with community members and researchers

- Enable a person or group of people to make their own independent, well-informed decision about whether they will be involved in CEI and how
- Ensure that researchers develop a good understanding of why community members choose to take part in CEI
- Promote transparency and accountability in CEI
- Help to develop a mutual agreement between community members and researchers about how an engagement process will be undertaken

submit

You can find more important points to consider with respect to incorporating ethics into CEI in health research in Adhikari *et al.* (2020), Hickey *et al.* (2022), and Nouvet *et al.* (2022). See References in Lesson 13: Summary, for full details.

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# Transparency

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## **Accountability, relationships and trust**

Incorporating ethical principles into CEI allows for [transparency](#) in engagement. It provides the basis on which research teams and individual researchers are **held to account** by communities.

Transparency in CEI means being continuously **clear and open** about the research process and research engagement activities with all stakeholders.

Being transparent in CEI helps to manage expectations, reduce misunderstanding and **build trust** between researchers and community members.

### **Plans, goals and management of expectations**

Transparency in CEI involves being **clear and open** about:

*Select each picture to flip it for further information.*



What can be achieved through a research project or programme, together with the constraints on the project.





The role and influence community members will have in:

- decision-making within research

The following case study provides an example of the role and influence community members can have in CEI.

*Select the green button to open the resource.*

### **Black & Sykes 2022**

Black, G. F. and Sykes, P. (2022) 'Steps toward engagement integrity: Learning from participatory visual methods in marginalized South African communities.' *Frontiers in Public Health* 10: 794905.

**BLACK & SYKES 2022**

### **Compensation**

Transparency in CEI also involves being clear and open about [compensation](#) for participation in engagement activities.

When community members are engaged as co-researchers, members of steering committees, or in other participatory CEI, including

workshops, training sessions or [capacity development](#) activities, they should receive appropriate compensation.

The level of compensation being offered should be **discussed and agreed from the start**; for example, at an introductory meeting (see Lesson 3: Incorporating ethics into CEI).



It is important to recognise that compensation for participation in CEI:

- can be harder to organise, administer and monitor when large numbers of community members are involved;
- may influence an individual's decision to take part in CEI activities.

Compensation should be tailored to the particular setting. An example is given in the next case study.

CEI, including discussions with community leaders and other community members, can help researchers understand what type of compensation would be appropriate and acceptable locally.

### Case study:

In a study of mass antimalarial drug administration (MDA) in Laos,



community members advised the research team

to provide household items such as cooking utensils to CEI participants, rather than monetary compensation.



Take a few moments to consider the following questions.

1

Can you think of a non-monetary form of compensation that would be appropriate, feasible and helpful to offer community members for participating in CEI activities in your setting or project?

2

What ethical challenges do you foresee with this approach to compensation?

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### Research challenges

Watch the video below about two research teams in South Africa conducting research in the same setting. Whilst watching, consider what challenges the second research team had and why.

*Select the play symbol below. Closed captions are available by selecting 'CC'. The transcript can be viewed underneath by selecting the '+' symbol.*



## Video Transcript

A biomedical research team in South Africa won a large research grant to investigate links between tuberculosis (TB) and diabetes.

As part of their study, the researchers invited an established group of community health volunteers from a local township to become involved in an 18-month CEI programme. The researchers provided generous compensation for the members of the community group to participate in workshops and events.

Some months later, a different research team won a small grant to explore the immune response to Covid-19 in the same research setting. As part of their research study, the researchers asked a community safety group from the same local township to become involved in a 6-month CEI programme. The research budget included [token compensation](#) for participation in a small number of meetings.

The Covid-19 research group was unable to retain a committed group of community members to take part in their planned CEI.

What factors do you think could have led to the failure of the Covid-19 team to engage successfully with the community?

*select all that apply then select 'submit'*



submit

*A transcript of the video explaining the answers can be viewed below by selecting the '+' symbol.*

### **Video Transcript (activity answers)** —

The research teams were working in the same research setting, so the information about the amount of compensation provided by the first research group probably reached the entire community.

Whereas the first research team engaged community members who had an established concern in health matters, the second research group engaged community members who were activists

for safety in their community and may not have had sufficient time to be involved in the C.E.I. programme or have a keen interest in health.

The C.E.I. programme for the first research project was longer and would therefore allow more time for information exchange between researchers and community members and a deeper opportunity for meaningful engagement and involvement.

### **Change, challenges and documenting**

As well as considering transparency in relation to accountability, goals, expectations and compensation, it is also important to be transparent about:

- any **changes** to the planned CEI that were discussed and agreed with community members at the outset;
- any **difficulties** that arise and may hinder or prevent CEI from going ahead as planned.

To further strengthen transparency, ethical CEI requires the opinions and ideas expressed by community members to be recorded and responded to (see Lesson 7: Adaptive research cycles).

**CONTINUE**

# Consent to participate in CEI

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A further crucial component of ethical CEI in research is [informed consent](#).

Not all CEI activities require participants to give formal written consent, **however**, the need for a formal or informal consent process should be carefully considered.

### **Informed consent**

Whether formal (documented) or informal, consent should always be well informed, requested by researchers or CEI teams in an unbiased manner and discussed in the first language of the CEI participants.

Information provided about CEI activities during both formal and informal consent processes should include clear details about:

- **what** participation in CEI will involve (see Lesson 3: Incorporating Ethics into CEI);
- the **aim** of the CEI activities;
- the envisaged **outputs** of the CEI activities;
- an explanation of **who** is eligible to participate;
- the **time** commitment for community members;

- the **role of the researchers** and/or the CEI team;
- the **role of community members**;
- **how** information collected during CEI activities will be used, and that it may be used to inform ongoing CEI and the research process;
- whether or not there is **compensation** for time spent, including the amount, if monetary, to ensure transparency.

**Formal (documented) consent** to participate in CEI is required to protect all parties involved when engagement activities:

- include **deliberative consultations** where participant names could be shared with a wider audience;
- will result in the **creation of identifiable images** such as digital stories, films, photographs, posters etc. that could be shared with a wider audience;
- are being **studied and analysed** for the purposes of research and academic publication.

When formal consent is required, it should be documented using a consent form.

## Consent forms

Consent forms should include all the information outlined above in the section on Informed consent. In addition, consent forms should:

- be developed in **consultation** with community members wherever possible;
- be written in the **first language** of the potential CEI participants;
- be made **available** to participants in hard copy or digital format depending on the circumstances or setting of the CEI;
- include a section at the end where community participants can indicate their **permission** and approval to be involved in CEI activities.



An additional multimedia release form is essential when the researchers or CEI team wishes to share identifiable images of community participants with **wider audiences** (see section on Level 1 and Level 2 consent, below). Consent for multimedia release can only be requested by researchers or the CEI team after the media in question has been created.



and school visits to research institutes. Community members can give informal consent to take part in CEI as **verbal permission**.

*Select the 'start' button, followed by the right arrow to navigate through the slides.*

Additionally, it is important to consider:

1



Whether the community members attending your consent activity understand that participating in CEI is not compulsory.

Potential CEI participants should not feel pressured by anyone to take part.





If community leaders know and accept that participation in CEI is voluntary.

Potential CEI participants should not be penalised in any way if they chose not to become involved in engagement activities.



How to ensure the expectations of community members are understood and well managed.

For example, the consent process should provide clear information on how health service provision may change (or not) as an outcome of the engaged research activities.



That researchers' expectations of the CEI are understood and managed.

For example, participation in CEI does not mean that community members will go on to consent to participate in the research study.

## Level 1 consent

in CEI involves community members **giving informed permission** to take part in research engagement activities. Level 1 consent can be sought in writing (formal) or verbally (informal) depending on the nature of the engagement process.



## Level 2 consent

involves community members giving their approval for the **use of written or visual materials developed during their CEI participation**. Level 2 consent is a formal written process requiring completion of a multimedia release form.



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Which consent level?

Read the following scenarios and select the correct consent level.

*Select 'next' to choose level 1 or 2.*

 Thumbnail

Further crucial points to consider in relation to informed consent processes can be found in the resources below.

*Select the green button to open the resource.*

**Emanuel *et al.* (2005)**

Emanuel, E. J., *et al.* (2005) 'Undue inducement in clinical research in developing countries: is it a worry?' *The Lancet* 366(9482): 336-340

EMANUEL ET AL. 20...

**Molyneux & Bull (2013)**

Molyneux, S. and S. Bull (2013). 'Consent and community engagement in diverse research contexts: Reviewing and developing research and practice: Participants in the community engagement and consent workshop, Kilifi, Kenya, March 2011.' *Journal of Empirical Research on Human Research Ethics* 8(4): 1-18

MOLYNEUX & BULL 2...

**Kamuya *et al.* (2017)**

Kamuya, D. M., *et al.* (2017). 'Gendered negotiations for research participation in community-based studies: implications for health research policy and practice.' *BMJ Global Health* 2(2): e000320.

KAMUYA ET AL. 2017

We will cover requesting consent for children to participate in CEI in more detail later in this module in Lesson 10: Minimising

harm (safety).

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# Inclusion

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Take a few moments to consider the following question and write down your answer:

When thinking about CEI, what does the word '**inclusion**' mean to you?

Inclusion in CEI happens when there is positive consideration of the obstacles that lead, or have previously led, to people, groups or communities being **excluded from engagement activities**, and action is taken to remove these obstacles (also see Lesson 10: Minimising harm (safety)).



Inclusion is about enabling people or communities to fully participate and access opportunities to engage.



Inclusive CEI aims to reduce power differences and reveal unconscious biases, and may influence the more powerful stakeholders to change or revise their ways of working.

When thinking through your CEI plans it is important to consider whether any of the participating community members may face **barriers** to engaging with you. These barriers could be personal, economic or cultural.

Review the factors below and decide which could pose barriers to inclusive CEI.

*Select all the barriers, then select 'submit'.*



poor health and illness	age	language
economic disadvantage	educational attainment	religion or belief
researchers' salary	size of CEI venue	race
literacy	employment status	evaluation outcomes
disability	ethnicity	stakeholder mapping
gender	culture	access to technology
equipment costs	vaccine storage conditions	access to transport
pregnancy	previous CEI experience	dietary requirements

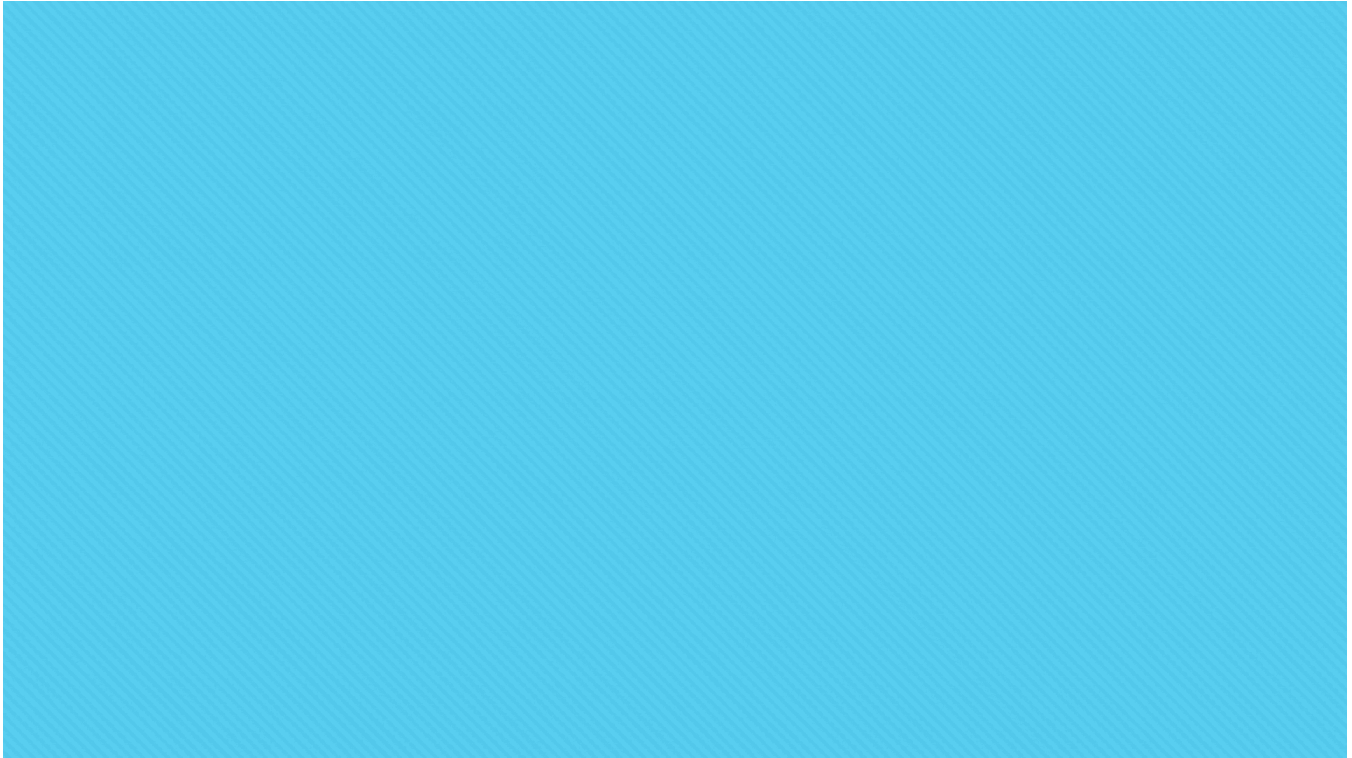
**submit**

Three ways to ensure inclusive CEI are:

- reframe your views;
- diversify your project team;
- create a safe and accessible space.

Watch the video below which gives further information and practical examples.

Select the play symbol below. Closed captions are available by selecting 'CC'. The transcript can be viewed underneath by selecting the '+' symbol.



## Video Transcript —

### **Reframe your views**

Rather than labelling a group 'hard to reach' and accepting that they have been excluded from CEI through lack of time, resource or access, ask yourself "Why do we find it hard to include these groups?"

#### Example in practice

As part of CEI in water microbiology research, a tribal craft group formed by women in Bangladesh was supported to create new folk art about their experiences of local environmental pollution. To enable their participation in these CEI activities, the art workshops were held in their usual meeting space in one of their homes.

### **Diversify your project team**

When planning your approach to CEI make sure discussions include community members and researchers who are representative of the different groups you are involving. Find ways to include vulnerable groups that are usually left out of discussions and excluded from decision-making. Work to understand the values of the whole community you intend to work in.

### Fictional example in practice

A project in Mali looking at the topic of female genital cutting brought together different stakeholders with a variety of views and set a strong ethos of open and non-judgemental communication, shared decision-making and a sense of common purpose.

### **Create a safe and accessible space**

Making activities accessible is not just about solving practical challenges like ramp access for wheelchair users, or ensuring posters are created in all local languages. Find ways to sensitively uncover reasons for lack of engagement.

### Example in practice

A service-user consultation assessing experiences of mental health provision in Kenya employed a mix of group or one-to-one, in-person or online discussion sessions, with flexibility around when the sessions took place. This enabled those living with different mental health issues to engage in ways that suited them.



Inclusion in CEI should be continuous and always evolving.

Careful planning, engaging with diverse stakeholders, learning from your mistakes and being conscious of your own bias will all contribute to strengthening inclusion.

Further critical points to consider in relation to inclusive CEI and science can be found in Lee *et al.* 2014 and Matias *et al.* 2021.

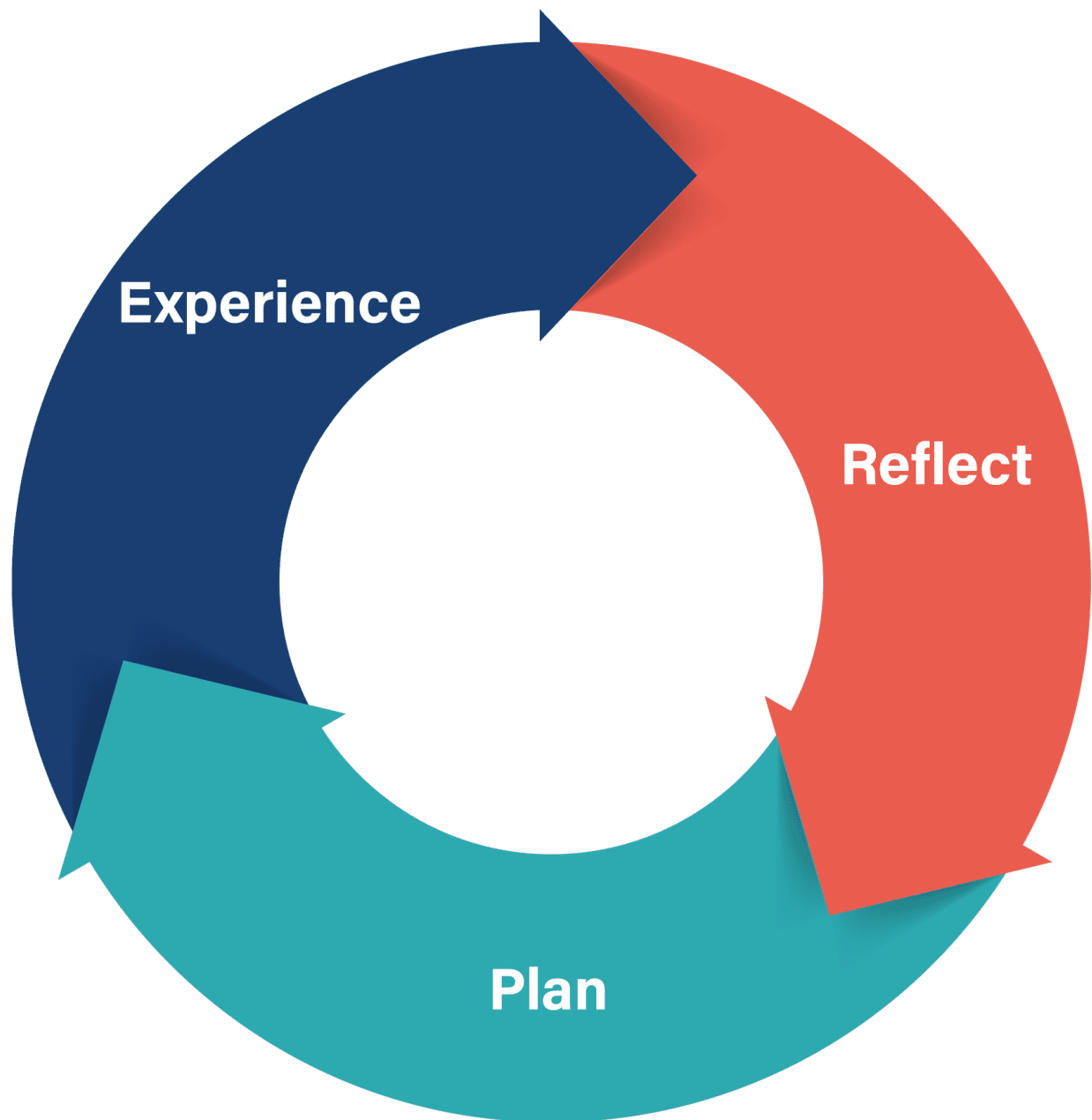
See References in Lesson 13: Summary, for full details.

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# Adaptive research cycles

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As explained in Module 1: Understanding CEI in Health Research, effective CEI requires researchers to actively listen to community experiences, including the expectations, concerns and challenges that may arise from research.



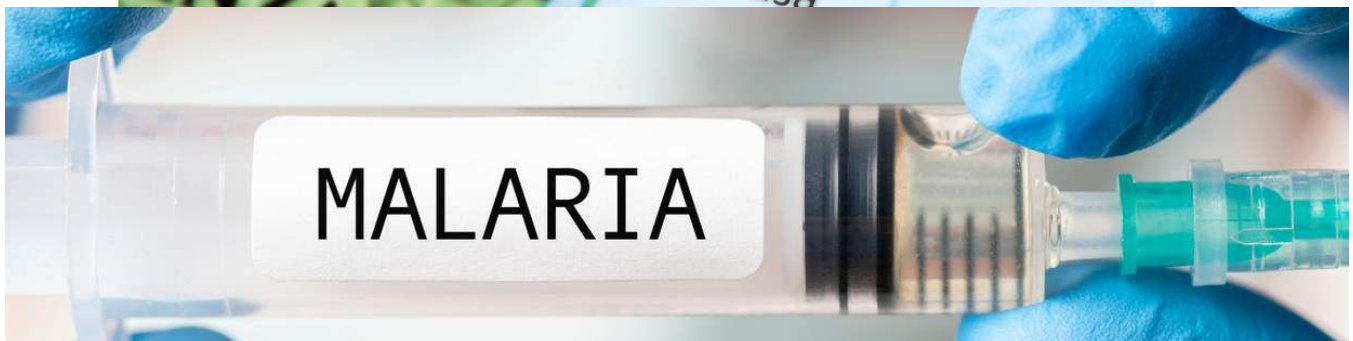
Being responsive to community feedback requires researchers to practice [reflexive learning](#) by thinking about their exchanges with community members (what has been discussed) and then adapting the CEI approach or research process as a result. These adaptations can be made as far as is reasonably practical in a given context.

This cycle of **continuous learning** enables the CEI and research to be adapted in a [feedback loop process](#).

Being open to reflexivity can help researchers think critically about how research is carried out and improved.

### **Case study: Human malaria infection, Kenya**

A research group in Kenya were undertaking pioneering studies using controlled human malaria infection. Their research involved deliberately injecting healthy research participants with malaria-causing parasites.





The research group were aware that human infection studies (HIS) can give rise to rumours which could threaten community trust and participation in health research.

The researchers worked with a team of community engagement specialists to develop a programme of CEI that included multiple phases of engagement with a range of stakeholders. Community members were involved in protocol development, and planning and implementation of the study.





The continuous CEI activities enabled the research group to respond to community feedback (including any myths or misunderstandings) in

cycles, and incorporate their learning into each phase of the study design (Mumba *et al.*, 2022).

## CONTINUE

### Challenges

As illustrated in Module 1: Understanding CEI in Health Research, CEI has a wide spectrum of possibilities. The extent to which a research programme can be adapted in response to CEI activities will depend on the **type** of research study being conducted.

For example, changing the way a clinical trial is undertaken may not be possible due to global [protocols](#) that dictate clinical trial practice (see Module 4: Principles and Models for CEI). The explanation provided by a CEI team about why a research process cannot be adapted in response to community views, is a vital part of engagement, transparency and accountability.

#### *Mini case study*

During a CEI discussion, community members suggested that every participant in a clinical trial should be given the research (experimental) vaccine instead of 50% receiving a placebo. The

CEI team needed to unpack and explain the concept of '[equipoise](#)' and clarify why a [placebo-controlled](#) trial is the necessary design in a [clinical trial](#) like this.

Educational background, professional bias and varying degrees of decision-making power within research teams may also influence how, and if, the views emerging from CEI are actually incorporated into a research process.

The researchers' ability to respond to suggestions made through CEI may also be restricted by [structural constraints](#), such as [socioeconomic](#), cultural or political boundaries.

For example, community members living in an urban informal settlement may request researchers to install standpipes (taps) in the settlement to enable access to a piped water system. It is likely that political and infrastructural constraints will prevent the researchers from being able to fulfil this request.



In learning about adaptive research cycles, we have discovered that opportunities to undertake CEI, or to be reflexive in a CEI process, can be limited by a lack of researcher buy-in or power, structural constraints within the research context, or the type of research that is being carried out.

- i In these kinds of situations, it is important to design your approach to CEI accordingly so that community members can be engaged and involved in research in ways that are meaningful and allow their experience and aspirations to be influential.



This can be achieved by including community members in, for example, community advisory boards (CABs), [research translation processes](#), or training activities to strengthen [research literacy](#) and build local skills in research methods.

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# Power dynamics in CEI

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In this section, we explore why it is necessary to understand [power dynamics](#) in the community settings you are working in, and how these can be navigated, giving examples. We also look at power dynamics that can arise between community groups and researchers, and between researchers and engagement practitioners, in the context of CEI.

Thinking back to the community settings you work in, which areas of power dynamics could affect successful implementation of CEI activities?

## **Understanding power dynamics in the context of the community**

CEI practitioners, as well as researchers, must develop an understanding of community structures in the areas they carry out research studies. In most regions of the world, there are governance and societal/cultural structures that determine

power and decision making. In low and middle income countries (LMICs) for example, individuals typically belong (but are not limited) to:

- A geographical location
- A patient group
- A professional body (such as medical associations)
- A cultural/ethnic/societal group (such as kingdoms/clans/castes)

An individual might belong to more than one of these groups. In each grouping, it is important to **map** out the power, gender, societal and cultural dynamics, to ensure meaningful engagement and involvement of all.

Other dynamics that can impact engagement include:

- The persisting influence of colonial legacies (experiences and histories) in LMICs.
- Differences in power in terms of literacy, wealth, understanding of biomedical concepts and decision-making power.

- Vulnerable groups that are usually left out of discussions and decision-making, for example, children, women, persons with disabilities and [LGBTQIA+](#) people.



Structural, economic and/or societal inequalities can lead to ethically-flawed engagement practice. These inequalities could result in voices of the most **vulnerable** being left out in global health research planning and implementation. Consequently, vulnerable groups remain 'powerless' in research decision making.



## CONTINUE

### **The role of gender, culture and societal norms in CEI**

CEI practitioners and researchers must first seek to understand the different power dynamics in a given local context that influence cultural and societal norms, as these can impact how well engagement is done.

#### **Example in practice**

The community in Kilifi, Kenya is [patriarchal](#). When community engagement was introduced as essential practice at the Kenya Medical Research Institute in Kilifi, from the start deliberate efforts were made to ensure participation of women in community engagement activities.



For example, in electing community advisory board (CAB) members, one key [criterion](#) was a 50/50 split in membership between men and women.



During engagement meetings, moderators used pre-agreed ground rules to ensure every CAB member had an equal opportunity to contribute.



Examples of meeting/training/workshop ground rules:

- 1) Participants should respect each others' opinions
- 2) Respect time allocations during the meeting
- 3) All attendees should participate actively in the workshop/training/meeting
- 4) Minimise movement in and out of meeting room

5) Keep mobile phones on silent mode/minimise disruptions during meeting/training/workshop

When preparing for CEI in a particular setting you should consider the following:

- Which are the main **institutions** in that area (for example, ministry of health, local administration)?
- What is the **influence** of political figures?
- What **cultural structures** exist (for example, role of religious leaders, traditional leaders)?
- If it is a particularly patriarchal area, consider how to include women and children.
- Are there groups representing the most vulnerable, and are they truly representative? Do the groups have vulnerable individuals within their membership or leadership? See Lesson 6: Inclusion.
- What are the **do's and don'ts** of first contact with a particular group (for example, in Kenya you would need to pay a courtesy visit to a local administrative Chief, prior to beginning engagement activities in the local area)?

- Do men, women and young people sit together?  
Can women and youth speak in a forum where men are present?



**CEI is political, so an important note:** CEI

processes are by their nature political processes, whether researchers see them as such or not. It is crucial to be mindful of power dynamics among a group of people. When power dynamics related to gender and culture, especially, are not adhered to or well managed, CEI activities can lead to conflict in an institution, locality, or even village (or group). Ethical conduct of research or engagement activities cannot happen in an environment of conflict.

**CONTINUE**

## **Understanding power dynamics within community groups: who speaks for the community?**

Achieving **fair and typical representation** in community groups is a challenge. Below are some tips to help understand the different power structures in a community.

*Select the 'start' button, followed by the right arrow to navigate through the slides.*

Tips for understanding the different power structures in a community.





Undertake consultative stakeholder mapping or [Rich Pictures](#) of the range of people/groups in a given community (see Module 2: Justifying CEI, Considering Stakeholders and Engaging Policymakers).



Work together with the community to determine who represents the different groups in that area.



Conduct [Key Informant Interviews](#) with selected individuals in the community, taking care to ensure vulnerable groups are not left out.



Jointly agree on ground rules in meetings and events to enable free speech from all groups.



Understand that 'leaders do not always speak for their people'. Therefore, it is important to ensure that even after speaking with opinion leaders, mechanisms are put in place to listen to the people themselves, for example, through large community meetings.

**Case Study: Fair and typical representation of CAB members**

When starting to form a Community Advisory Board (CAB), a research institute identified and selected 'community representatives' from Community Based Organisations (CBOs) in the host community. Most of these representatives were

identified from the executive of these CBOs (for instance, Chairperson, Secretary, or Treasurer). When these members were presented to the community in a large community meeting, community members rejected them, stating that they did not represent their views. The research institute's CEI team worked with local community members to change the CAB membership.

In these situations, key considerations include (but are not limited to):

- 1 The importance of listening and responding to concerns raised.
- 2 Flexibility is key - sometimes community members will not agree with your plans.
- 3 It is important to keep channels of communication open for continuous feedback on the process of selecting CAB members.

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**Navigating power dynamics within community groups and managing power from opinion shapers**

## or leaders

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### Managing power - what would you do?

Read the scenario below, and consider the questions raised.

*Select 'next' to move from the scenario to the questions.*

As a researcher, you have attended a community meeting organised for you by a local Chief. In the meeting, you speak about a malaria clinical trial that you will soon start in the area. Parents will be required to volunteer their babies to take part in the research. At the end of your engagement session with community members, the Chief makes closing remarks. They thank you and instruct all mothers to register to participate in the clinical trial. He goes on to say that all mothers who refuse to participate will be removed from a food stamp programme run by the World Food Programme.

next

What is your (the researcher's) immediate reaction to the Chief's instruction?

You realise the mood of community members has changed after the Chief's statement, and you are worried this will impact your recruitment. What would you do to ease any tension?

What are the ethical implications of the Chief's instruction?

There is unfortunately no one prescribed way of handling difficult situations as they occur in the community, during engagement activities. For instance, in this case where a leader

attempts to 'coerce' community members to participate in research, the following actions by the researcher may depend on the existing relationship with the leader.

Examples of responses could include:

- Speak immediately after the leader has finished and, with diplomacy, provide the right information, without making the leader feel undermined before his people.
- If seated next to the leader, politely give him the right information and request him to make the correction before the meeting formally ends.

As a research team you must remain calm and composed in such instances, and avoid openly putting down the leader in the presence of their community members.

**CONTINUE**





**Understanding power dynamics in the context of CEI**

Power dynamics exist within all groups involved in or affected by research. These include:

- within communities,
- between communities and researchers,
- between researchers and CEI teams, and
- within research teams.

### **Power between community groups and researchers**

Researchers are seen as wealthier and more powerful, especially in poorly resourced environments. Careful consideration must be made to build relationships where communities feel genuinely respected.

*Select each of the tabs from left to right to learn more.*

**TERMS OF ENGAGEMENT**

**THE ROLE OF LANGUAGE**

**COMPENSATION AND  
PAYMENTS**

[Terms of engagement](#) must be set collaboratively. Even where such terms are set by CEI staff, there must be forums for getting input and

recommendations from communities, followed by feedback on how their recommendations have been taken up.



**TERMS OF ENGAGEMENT**

**THE ROLE OF LANGUAGE**

**COMPENSATION AND  
PAYMENTS**

Researchers can be trained to use simple terms/language during engagement events. CEI activities must be undertaken in a language best suited to the audience, including use of the vernacular. Where a researcher is not familiar with the language, a translator can provide support. However, it is important that the researchers do engage directly with communities, even if there are language barriers.



**TERMS OF ENGAGEMENT**

**THE ROLE OF LANGUAGE**

**COMPENSATION AND  
PAYMENTS**

There is a danger that community members can be [disempowered](#) because of payments/compensation received for participating in CEI activities. Careful explanation should be given regarding payments (refer to Lesson 4: Transparency), and emphasis put on community members being able to freely give their feedback or share their views without fear of losing out on this perceived 'benefit'.



### **Power between researchers and the CEI practitioners**

Read the scenario below and think about the implications of the research team leader's decision. What concerns would you have?

You are a CEI practitioner hired to work within a clinical trial and are responsible for meaningful engagement of all communities and stakeholders relevant to the project. Your research team leader is

being pressured by sponsors to start recruitment and has instructed you to only hold engagement meetings with the local ministry of health team.

The research team leader argues that community members will be sufficiently engaged through the study participant informed consent process for the clinical trial, where they will have an opportunity to ask questions to better understand the trial. They also feel other local leaders can be engaged at a later stage as the trial goes on and when the study team has time.

The research team leader is not your direct line manager, but authorises the money that pays your salary.

Sometimes study timelines can clash with engagement activity implementation, and this can happen when investigators are pushed by sponsors or funders to start trials.

You may have thought of the following, or, indeed, other ideas, to help manage this situation.

*Select each of the tabs from left to right to learn more.*

**HIGHLIGHT THE IMPORTANCE**

**STAKEHOLDER MAPPING**

**ENGAGEMENT PLAN**

During study meetings, highlighting the importance and advantages of involving key community stakeholders can help research leaders advocate for more time for CEI from sponsors or funders.



**HIGHLIGHT THE IMPORTANCE**

**STAKEHOLDER MAPPING**

**ENGAGEMENT PLAN**

As a CEI coordinator, from a very early stage you can map the key stakeholders including community groups, prioritise them, start to engage with the most crucial stakeholders, and then continue to bring in others throughout the study. This way, all the CEI does not need to be completed before the project commences.



**HIGHLIGHT THE IMPORTANCE**

**STAKEHOLDER MAPPING**

**ENGAGEMENT PLAN**

Developing an engagement plan early on, and collaborating on this with the research team, can also be helpful. Doing so gives ownership of the CEI planning to the whole team, reinforcing its value within the whole study, and reducing the likelihood of resistance when there are time pressures.





You can read about other important considerations in relation to power and CEI in research in Pratt (2019), Pratt (2020), and Pratt *et al.* (2022).

**CONTINUE**

# Safety

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In this section, we discuss requirements for participant anonymity and confidentiality. We consider the importance of identifying vulnerable individuals and the need to safeguard against increased marginalisation. Next, we explore how to ensure ethical conduct in CEI with children. Finally, we explore the safety around data sharing.

**CONTINUE**

## Minimising harm (safety)

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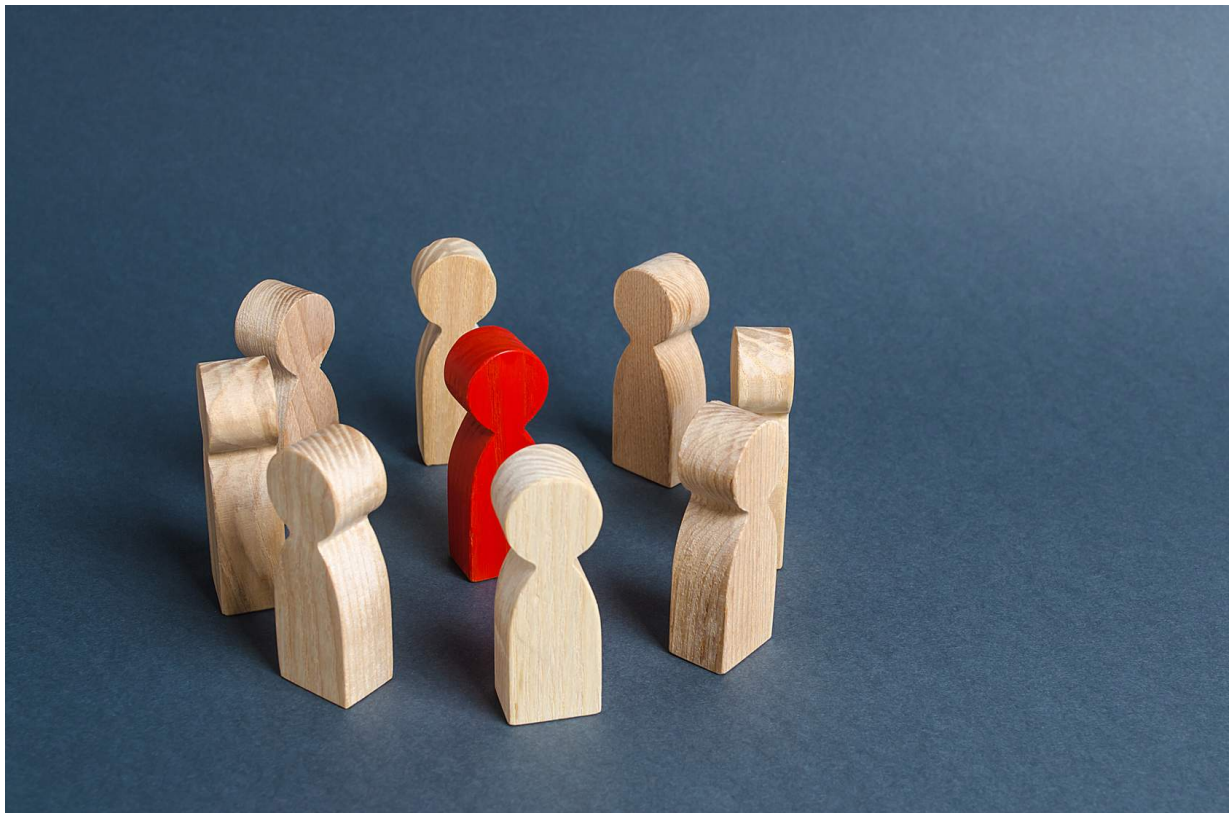


### **Participant anonymity and confidentiality**

While conducting CEI, it is important to maintain [participant confidentiality](#). Information collected during CEI can be **anonymised** to ensure that individuals cannot be identified. In cases where participants want to be or can be identified, for example where photographs, audio recordings, or films are produced, then appropriate consent must be

taken. This can be group or individual consent (see Lesson 3: Incorporating ethics into CEI).

Filming or photography that threatens people's dignity must be avoided. Electronic databases or files that store personal information of, for example, Community Advisory Board members, must be **password protected** and where possible **encrypted**. Personal information includes details such as names, addresses, telephone numbers, education level and marital status.

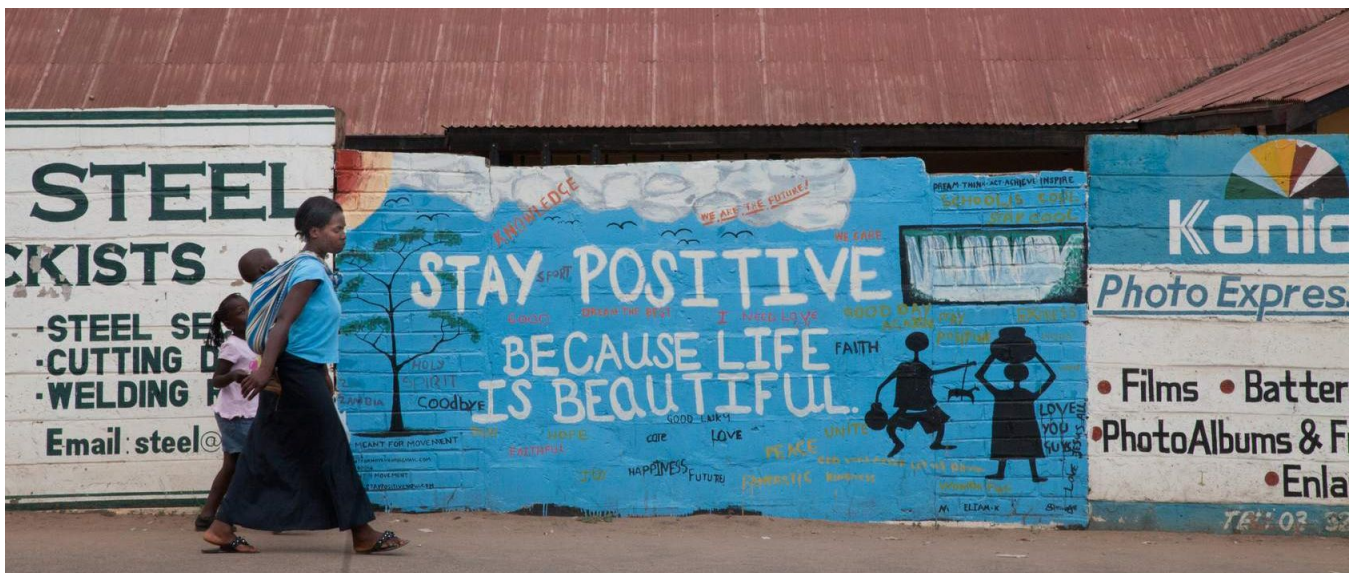


Sometimes, CEI aimed at supporting specific research projects can inadvertently reveal members of the community who have certain vulnerabilities. For example, engagement for research studies on sensitive health issues that are often accompanied by varying levels of

stigma and discrimination – such as HIV, epilepsy and mental health – must be carefully undertaken to avoid causing further harm.

- i** A CEI plan or strategy must include a section or sections which outline how individuals or communities will be protected. Institutions may already have policies and systems in place that support anonymisation of data, confidentiality and Data Protection. Where these do not exist, it is important to ensure these policies and systems are put in place before commencing CEI activities.

More about data protection can be found in the UKRI overview of GDPR and research (2020) (see Further Resources in Lesson 13: Summary).



## **Safeguarding against further marginalisation**

Labelling of community groups can increase their vulnerability. This can happen when vulnerabilities are used to **exclude** certain groups from CEI. For example, setting up CEI activities without considering access needs for people with hearing or sight disabilities means such groups are left out of important discussions about their own health. When mapping of community groups is done well, knowledge of these groups can help CEI practitioners to create inclusive opportunities which ensure that vulnerable individuals are not left out of research. Such groupings or labels include, but are not limited to: pregnant women, people with mental or physical disabilities, children, young people, people who cannot read or write well, people with low socio-economic status and key population groups (in HIV programming) such as sex workers.

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### Barriers associated with participating

Think about the area/locale where you are based (or where your research institute or team conducts research). Can you identify any vulnerable groups that have perhaps been left out of CEI activities?

Below are some suggestions for how burdens or barriers associated with participating in CEI activities could be minimised for such groups.

### How can burdens or barriers associated with participating in CEI activities be minimised for such groups?



easily accessible venues (with ramps, disabled toilets, [hearing loops](#))



using appropriate communication tools and language (large reading fonts, coloured paper, translators, braille, sign language)

select each of the circles



seeking appropriate permissions for engagement (for example with minors)



providing compensation and reimbursement for inconveniences experienced by participating in CEI activities (travel costs, missed work opportunities and so on)

### Engagement with children

Most children want their voices to be heard when it comes to decision-making about CEI or research participation. Some institutions have set up Young Persons Advisory Groups (YPAGs) to help bring views of children into research planning and implementation.



Tailored approaches used in engagement with children include science [symposiums](#), debating competitions, theatre performances, arts workshops and researcher mentorship sessions. As children may not have the ability to fully understand and therefore fully consent to activities, the following must be carefully considered, and necessary strategies put in place to counter any potential negative impact:

- Materials used must be **suitable for their age**: content must be within the skill-set and knowledge of children for them to be able to meaningfully participate.



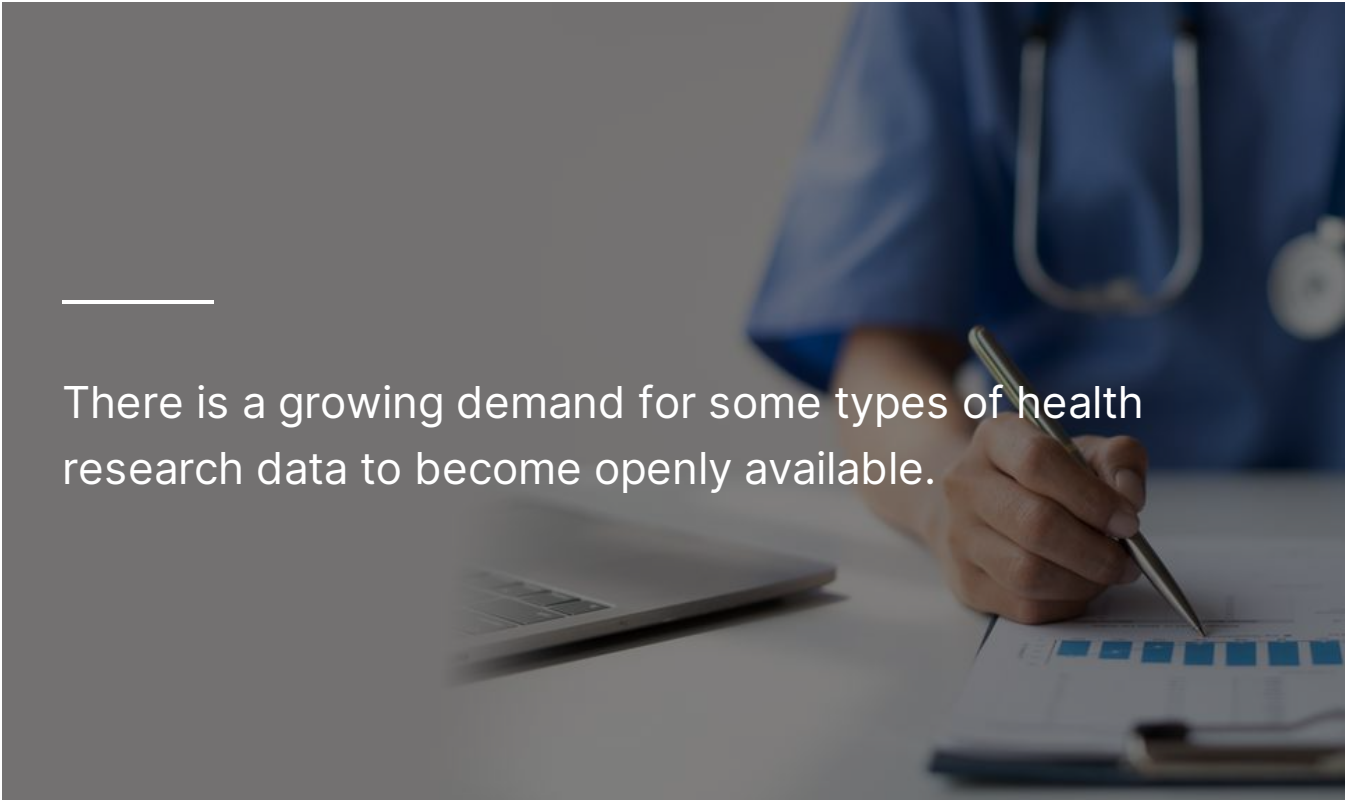
- Parents/guardians can give **consent** for child participation. However, minors must be given an opportunity to give their consent first.
- The need to **protect children from discrimination** arising from non-participation in CEI activities (for example, a teacher punishing a student for refusing to participate in a CEI event).
- Children must be **protected from encountering abuse or harm** in the course of participating in CEI activities (institutions/research projects must put in place safeguarding policies).
- Adults coming into contact with children during CEI should, if possible, be vetted (background criminal record checks) to minimise the risk of potential [perpetrators](#) coming into contact with minors.

Further crucial points to consider in relation to engagement with children can be found in Marsh *et al.* (2019). See References in Lesson 13: Summary, for full details.

**CONTINUE**

## Data sharing

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There is a growing demand for some types of health research data to become openly available.

For health research projects where data sharing is a requirement, ethical CEI necessitates the engagement of participants and other community stakeholders on the topic of data sharing and in developing a data sharing policy.

Encouraging the community to take **ownership** of the data sharing policy supports transparency and helps to build trust between researchers and research communities (see Lesson 4: Transparency).



Patients and other community stakeholders involved in developing a data sharing policy are likely to take part in facilitated discussions about:

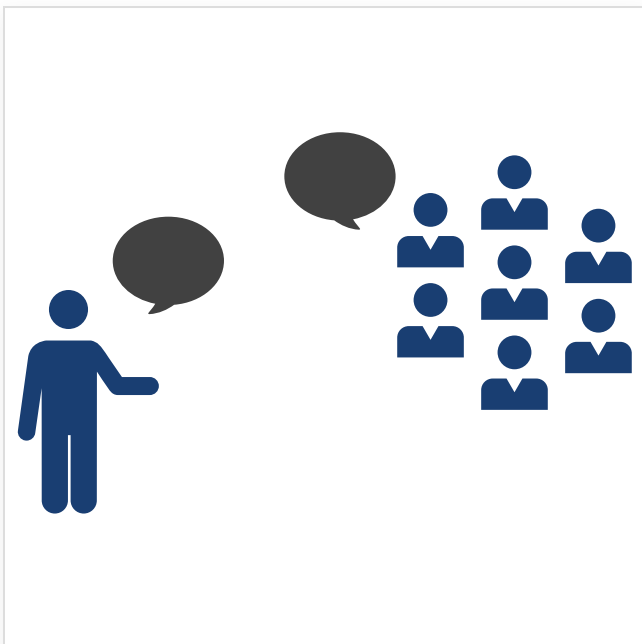
- how data will be collected and used,
- the risks, benefits and other relevant implications of sharing health data,
- the ethical considerations of data collection and data sharing,

- why developing a data sharing policy and formulating data sharing agreements is important.

CEI in developing a data sharing policy should be **inclusive**, allow different groups to participate and have equal opportunities to voice their perspective and ideas (see Lesson 6: Inclusion).

Shared accountability in data sharing CEI requires the following:

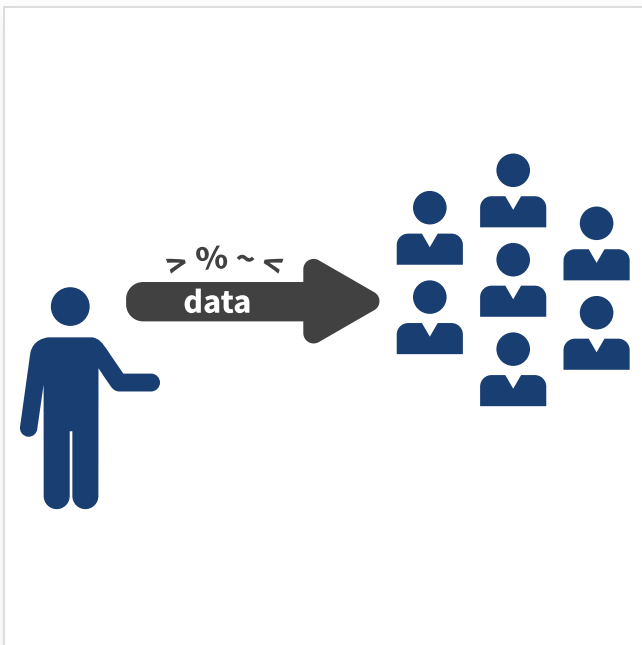
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Researchers and study communities to discuss and agree upon appropriate means of communication and feedback.



Researchers to provide feedback to study communities about the progress and outcomes of health research projects in which they are involved.



Researchers to provide feedback to study communities about how data is currently being used.

Many countries have official data sharing and data transfer policies in place, and research practice should always adhere to such policies. For example, in South Africa, the Protection of Personal Information Act (POPIA, 2013) has been implemented

to 'give effect to the constitutional right to privacy, by safeguarding personal information when processed by a responsible party'.

The South African POPIA Act can be found in Further Resources in Lesson 13: Summary.

### **Capacity development**

For communities to meaningfully contribute to research planning, data collection and [dissemination](#) of findings, it is important to provide **training** for patients and other community stakeholders in data sharing policy development.

CEI in data sharing further challenges research teams to move from thinking of people as patients or research participants and instead see research communities as agents who can make informed decisions about the primary and secondary uses of their data for the benefit of their communities.

Further crucial points to consider in relation to CEI and data sharing can be found in the resource below.

*Select the green button to open the resource.*

**Maya Sabatello *et al.* (2022)**

Maya Sabatello *et al.* (2022). Data sharing and community-engaged research. *Science* 378,141-143  
doi:10.1126/science.abq6851

MAYA SABATELLO ET...

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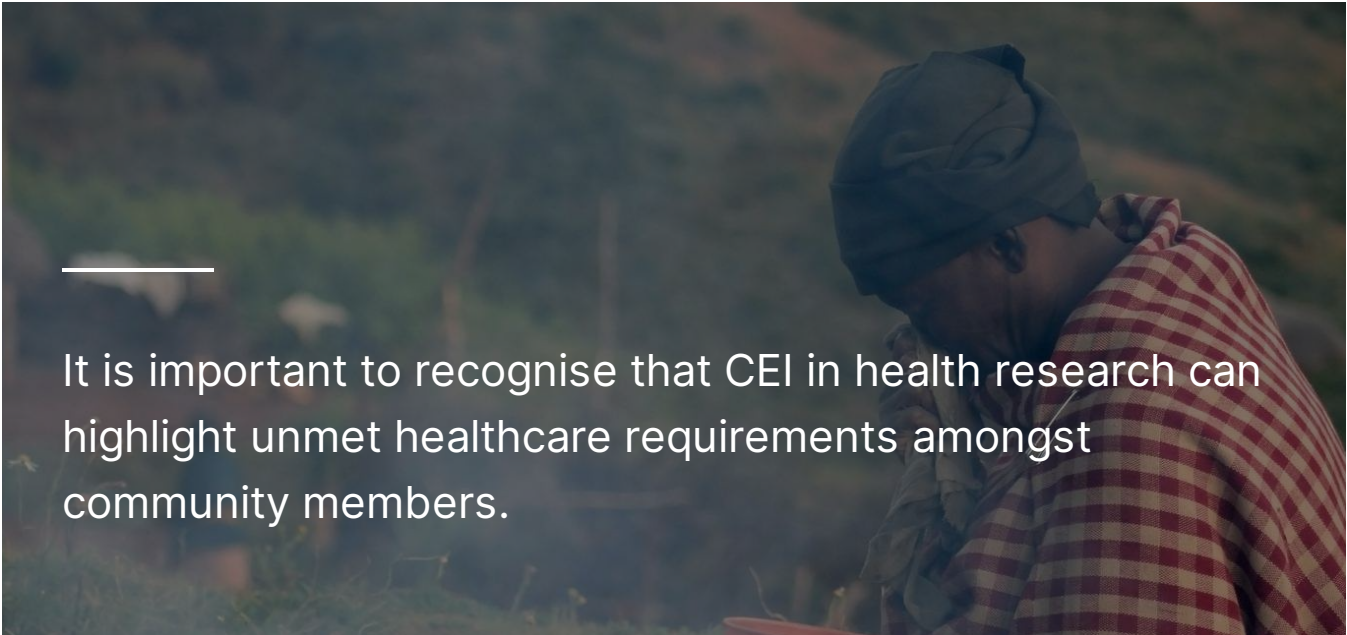
## CEI and healthcare provision

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In this section, we briefly discuss the importance of CEI in highlighting unmet healthcare requirements amongst communities, and the research teams obligations.

**CONTINUE**

### CEI and healthcare provision




It is important to recognise that CEI in health research can highlight unmet healthcare requirements amongst community members.





When unmet health needs are brought to light through community participation in CEI activities, CEI facilitators should inform the health researchers or health professionals in the research team so that appropriate action can be taken.

The research team can decide how best to respond depending on the circumstances, context and particular focus of the health research.

 Ethics guidelines are available to assist researchers to understand their ethical obligations and make decisions about how to respond to community healthcare needs, including health needs that are beyond those of the health challenge being researched.

*To view the resource, select the green button.*

### **Guidelines**

Council for International Organizations of Medical Sciences (CIOMS) (2016) *International Ethical Guidelines for Health-related Research Involving Humans*.

## Examples of healthcare provision in CEI



### CEI meetings with CAB or community members

Public Health Officers attached to primary healthcare facilities (Dispensary or Health Centre) are invited to attend CEI meetings with CAB or community members.

During such meetings, research studies are discussed and then at the end of the meeting, community members are encouraged to share any other concerns they might have.

During this final session of the meeting, any concerns shared around healthcare service provision (e.g. lack of drugs, long waiting periods, inadequate healthcare workers), are addressed by the public health officers, or other local department of health staff in the meeting.

### **Health and research radio programmes**

In health and research radio programmes, it has been found that listeners are more concerned about their immediate health problems.

Health and research radio programmes have therefore helped to refer listeners who call in to share health problems, to nearby health facilities/hospitals, for medical attention.

For example, in some calls, listeners have shared possible symptoms they or their relatives are experiencing, with researchers on air and have been given medical advice or have been encouraged to go to hospital for medical attention.



The following study provides an example of the importance and influence of providing primary health care as part of a research project with a specific health focus.

*Select the green button to open the resource.*

**Adhikari *et al.* (2018)**

Adhikari, B., et al. (2018). 'Why do people participate in mass anti-malarial administration? Findings from a qualitative study in Nong District, Savannakhet Province, Lao PDR (Laos).' *Malaria journal* 17: 1-13. doi: <https://doi.org/10.1186/s12936-017-2158-4>

ADHIKARI ET AL. 2...

**CONTINUE**

# Summary

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In this module, we have explored:

- How to apply ethical principles in CEI

- Why transparency, consent and inclusion are important elements of CEI
- How CEI can inform adaptive research cycles
- Forms and implications of power dynamics in CEI
- Key principles of safety in CEI
- The importance of ethics in data sharing
- How CEI can respond to healthcare needs that have not been met

**CONTINUE**

## Further resources

### Incorporating ethics into CEI

#### Book chapter

Mathers, N., Howe, A. and Hunn, A. (1998) 'Autonomy', in *Trent Focus for Research and Development in Primary Health Care: Ethical Considerations in Research*.

**MATHERS ET AL. 19...**

### Resource guide

Nelson, E., *et al.* (2021) '*Ethical Dimensions of Community Engagement and Involvement in Global Health Research*', Resource guide, NIHR.

NELSON ET AL. 2021

## Inclusion

### Book

Burns, D., Howard, J., Ospina, S.M. (eds.) (2021) *The SAGE Handbook of Participatory Research and Inquiry*. London: SAGE Publications Ltd.

BURNS ET AL. 2021

### Book chapter

Mathers, N., Howe, A. and Hunn, A. (1998) '*Vulnerable subjects*' in '*Trent Focus for Research and Development in Primary Health Care: Ethical Considerations in Research*'.

MATHERS ET AL. 19...

### Resource guide

Nelson, E., *et al.* (2021) '*What does it mean to take a 'leave no one behind' approach to community engagement and involvement in global health research?*', Resource guide, NIHR.

NELSON ET AL. 2021

### Guidance document



NIHR (2021) *Guidance on co-producing a research project.*

NIHR 2021

### Report

Sachs, J., *et al.* (2020) *Sustainable Development Report 2020: The Sustainable Development Goals and COVID-19.*

SACHS ET AL. 2020

### Web page

Shaping Health (2018) *Exchanging on social drivers of health and wellbeing.*

SHAPING HEALTH 20...

### Web page

The World Bank (2017) *Social Inclusion.*

THE WORLD BANK 20...

## Power

### Resource guide

Nelson, E., *et al.* (2021) *'Ethical Dimensions of Community Engagement and Involvement in Global Health Research'*, Resource guide, NIHR.

NELSON ET AL. 2021

### Resource guide

Nelson, E. (2021) *'Empowering Meaningful Community Engagement and Involvement in Global Health Research: Critical Reflections and Guiding Questions'*, Resource guide, NIHR.

NELSON 2021

### Web page

World Health Organization (WHO) (2021) *Gender and health*.

WHO 2021

## Minimising harm (safety)

### Handbook

Black, G. and Chambers, M. (2019) *'The Practice and Ethics of Participatory Visual Methods for Community Engagement in Public Health and Health Science'*. Wellcome.

BLACK & CHAMBERS ...

### Web page

CLARISSA (2020) *Child Labour: Action-Research-Innovation in South and South-Eastern Asia*.

CLARISSA 2020

### Web page

UKRI (2020) *GDPR and research – an overview for researchers*.

UKRI 2020

## Data sharing

### Act of Parliament

Government Gazette (2013) '*Protection of Personal Information Act, 2013*'. Government Gazette Republic of South Africa. 581 November 2013

POPIA 2013

## CEI and healthcare provision

### Guidelines

Council for International Organizations of Medical Sciences (CIOMS) (2016) *International Ethical Guidelines for Health-related Research Involving Humans*.

CIOMS 2016

## References

All references for the module are available to download below.

*Select the grey box to download.*



**Reference list\_Module 3.pdf**

940.5 KB



**CONTINUE**

## **Acknowledgements**

Thank you to all who have been involved in creating the module content, its design and its testing. Thank you also to those who have kindly supplied images for use in this module and throughout the course.

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**CONTINUE**

# Congratulations!

You have now completed this module. Please select the link below to be taken to the end of module quiz.

[Module 3 Quiz: Ethical CEI](#)